IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

KNOLL PHARMACEUTICALS COMPANY, INC. and THE JOHN AND LOIS ARNOLD FAMILY LIMITED LIABILITY PARTNERSHIP,	)	
Plaintiffs,	)	Case No. 01C-1646
v.	)	Judge John W. Darrah
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

REPLY TO AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Plaintiff Knoll Pharmaceuticals Company, Inc. ("Knoll") and The John and Lois Arnold Family, Limited Liability Partnership ("Arnold LLP") (collectively "Plaintiffs"), respond and allege as follows:

AFFIRMATIVE DEFENSES

The allegations made in paragraphs 1-86 entitled "Affirmative Defenses" do not require Plaintiffs admission or denial. *See* Fed. R. Civ. P. 7(a). Nevertheless, Plaintiffs deny each of the allegations made in paragraphs 1-86 of Defendant's Affirmative Defenses.

COUNTERCLAIMS

1. Teva brings these counterclaims against Counterclaim Defendants Knoll Pharmaceutical Company, Inc. ("Knoll") and the John and Lois Arnold Family Limited Liability Partnership ("Arnold LLP") for violations of the federal antitrust laws and various state laws. (Knoll and the Arnold LLP are referred to collectively as "Counterclaim Defendants"). Counterclaim Defendants, acting with the purpose and intent to monopolize, embarked on a scheme to prevent Teva from bringing lower-cost versions of Knoll's prescription pain medication Vicoprofen® to market in the United States. Counterclaim Defendants' misconduct involved numerous improper actions, culminating in the filing and maintenance of sham litigation against Teva seeking to enforce United States Patent No. 4,587,252 (the "'252 Patent"). The lawsuit is an improper, knowing attempt to enforce a patent that the Counterclaims

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Defendants know was wrongfully obtained through fraud on the United States Patent and Trademark Office ("PTO"), and/or which the Counterclaim Defendants know to be invalid and unenforceable due to inequitable conduct. The lawsuit is objectively baseless and subjectively motivated by bad faith. The Counterclaim Defendants have filed and maintained the lawsuit not because they have a reasonable chance of prevailing on the merits, but because they hope to use the lawsuit as an anticompetitive weapon against Teva.

ANSWER: Plaintiffs admit that the Counterclaim purports to state a cause of action under the federal antitrust laws, but deny that Plaintiffs have committed any acts that violate the antitrust laws. Plaintiffs deny the remaining allegations of paragraph 1.

2. The manufacture and sale of Vicoprofen® and generic hydrocodone/ibuprofen products, including Teva's generic hydrocodone/ibuprofen product in the United States constitute a relevant product and geographic market. At the time of the actions alleged herein, Knoll was the sole supplier of hydrocodone/ibuprofen products to consumers in the United States. Counterclaim Defendants' improper conduct as alleged in these counterclaims constitutes an illegal attempt to monopolize the relevant market by excluding Teva from selling its generic hydrocodone/ibuprofen product in the United States. Counterclaim Defendants have acted to achieve their goal by misusing the regulatory framework for prescription pharmaceutical products with the specific intent of blocking Teva from bringing its lower-priced bioequivalent generic product to market in competition with Knoll's Vicoprofen® product. The Counterclaim Defendants' objective was to prevent any competition in sales of hydrocodone/ibuprofen products, allowing Knoll to continue to charge supracompetitive prices without losing market share, and allowing Arnold LLP to receive greater royalties as a result, to the detriment of both Teva and consumers.

ANSWER: Plaintiffs deny the allegations in paragraph 2.

3. Counterclaim Defendants had a dangerous probability of succeeding in their attempt to monopolize. Although Teva ultimately was able to thwart Counterclaim Defendants' scheme to monopolize by obtaining a favorable ruling on summary judgment in the sham litigation, Counterclaim Defendants' wrongful actions nonetheless caused and continue to cause substantial injury to Teva. Moreover, the injury to Teva from Counterclaim Defendants' wrongful conduct is "antitrust injury" – that is, the type of injury the antitrust laws were designed to prevent. Therefore, Teva brings this action under the federal antitrust laws to recover the losses it has sustained as a direct and proximate result of Counterclaim Defendants' wrongful conduct.

ANSWER: Plaintiffs deny the allegations in paragraph 3.

The Parties

4. On information and belief, Plaintiff and Counterclaim Defendant Arnold LLP is a limited liability partnership having a place of business at 8226 East Del Cadena Dr., Scottsdale, Arizona 86258. The Arnold LLP alleges it is the owner of United States Patent No. 4,587,252 (the "'252 Patent").

ANSWER: Plaintiffs admit the allegations in paragraph 4.

5. On information and belief, Plaintiff and Counterclaim Defendant Knoll is a corporation organized under the laws of New Jersey, with its principal place of business in Abbott Park, IL. Knoll was acquired by Abbott Laboratories in 2001. Knoll alleges it is the exclusive licensee of the '252 Patent from the Arnold LLP.

ANSWER: Plaintiffs admit the allegations in paragraph 5.

6. Defendant and Counterclaim Plaintiff Teva is a corporation organized under the laws of Delaware, with a place of business at 1090 Horsham Road, North Wales, PA 19454.

ANSWER: Plaintiffs lack sufficient information to form a belief as to the truth of the allegations in paragraph 6 and therefore deny the same.

Jurisdiction and Venue

7. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Antitrust Laws of the United States, 15 U.S.C. § 1 *et seq.*

ANSWER: Plaintiffs admit that the Counterclaim purports to state a cause of action under the Patent Laws of the United States and Antitrust Laws of the United States.

8. Jurisdiction in this Court is proper under 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

ANSWER: Plaintiffs admit the allegations in paragraph 8.

9. Venue in this Court is proper under 28 U.S.C. § 1391.

ANSWER: Plaintiffs admit the allegations in paragraph 9.

The Regulatory Structure for the Marketing of Generic Drugs

10. The manufacture and commercial sale of pharmaceutical drugs are regulated by the FDA pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (1994) (the "Act"). No branded or generic pharmaceutical drug may lawfully be sold commercially in the United States without the consent of the FDA.

ANSWER: Plaintiffs admit the allegations in paragraph 10.

11. Congress passed the "Hatch-Waxman Amendments" to the Act in 1984 after concluding, among other things, that the Act's drug-approval process delayed the entry of relatively inexpensive generic drugs into the marketplace.

ANSWER: Plaintiffs admit the Hatch-Waxman Amendments were passed by Congress in 1984. Plaintiffs lack sufficient information to form a belief as to the truth of the remaining allegations in paragraph 11 and therefore deny the same.

12. The Hatch-Waxman Amendments permit generic drug manufacturers to file an Abbreviated New Drug Application ("ANDA") that expedites the drug-approval process, principally because the ANDA may incorporate data that an earlier manufacturer has already submitted to the FDA regarding the earlier drug's safety and efficacy in a New Drug Application ("NDA").

ANSWER: Plaintiffs state that the allegations of paragraph 12 are legal conclusions to which no answer is required.

13. If an ANDA applicant seeks approval to market a drug before the expiration of any patent listed in the FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") that purportedly applies to that drug, it must make a certification for each such patent, according to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for

which the application is submitted." Such a certification is known as a "Paragraph IV certification."

ANSWER: Plaintiffs state that the allegations of paragraph 13 are legal conclusions to which no answer is required.

14. The filing of a Paragraph IV certification permits the holder of the patent identified in the Orange Book as covering the listed drug to assert a cause of action for patent infringement against the ANDA applicant. If such an action is brought within 45 days from receipt of notification of the Paragraph IV certification, the FDA cannot finally approve the ANDA until the earlier of 30 months from the patent-holder's receipt of notification of the Paragraph IV certification, the date on which the court that is hearing the patent infringement case holds that the patent is invalid, not infringed, or unenforceable, or the date on which the case is withdrawn, discontinued, dismissed, or otherwise terminated by the patent holder. The automatic 30-month stay is available only in circumstances where a Paragraph IV certification has been filed.

ANSWER: Plaintiffs state that the allegations of paragraph 14 are legal conclusions to which no answer is required.

15. If the holder of the listed patent does not file an infringement action within 45 days from receipt of the Paragraph IV notification, the FDA can finally approve the ANDA as soon as the FDA's regulatory requirements are satisfied.

ANSWER: Plaintiffs state that the allegations of paragraph 15 are legal conclusions to which no answer is required.

16. The automatic 30-month stay is maintained in place only by the continuous prosecution of the patent infringement suit and is abatable and terminable upon the patent holder's withdrawal, discontinuance, dismissal, or other termination of the patent infringement suit.

ANSWER: Plaintiffs state that the allegations of paragraph 16 are legal conclusions to which no answer is required.

17. The FDA approves an ANDA only when the ANDA satisfies all FDA regulatory requirements, including those relating to bioequivalence to the drug covered by the subject NDA. If the ANDA meets all FDA regulatory requirements and the ANDA applicant remains subject to a restriction on its right to sell the subject generic drug in the United States other than the adequacy of the ANDA, such as the 30-month stay provision, the FDA grants the ANDA applicant a "tentative" approval of the ANDA. Receipt of tentative approval does not permit the ANDA applicant to start selling the product in the United States. When the ANDA applicant is no longer subject to any regulatory restriction on its right to sell the subject generic drug in the United States, the FDA grants the ANDA applicant a "final" approval in place of the tentative approval. Following receipt of final approval, the ANDA applicant can commence sales.

ANSWER: Plaintiffs state that the allegations of paragraph 17 are legal conclusions to which no answer is required.

Counterclaim Defendants' Ongoing And Continuous Course Of Anticompetitive Conduct

Arnold's Fraudulent and Inequitable Conduct In Connection with the Prosecution of the '252 Patent

18. Teva repeats and realleges all of the allegations in ¶¶ 14 - 86 in Teva's affirmative defenses above, as though those allegations were fully set forth herein. In summary, during the patent application process John Arnold, the inventor of the '252 Patent and trustee of plaintiff The Arnold Family LLP, was aware of and had in his possession highly material prior art that rendered the claims of the `252 Patent invalid as anticipated or obvious. At minimum, that prior art was highly material and should have been disclosed to the Patent Examiner. Arnold and Costigan (the "Applicants") disclosed none of the material prior art in Arnold's possession, despite its clear materiality to Arnold's claims and despite their clear duty to do so. Applicants further, in distinguishing a prior art abstract of an article by Cooper, affirmatively misled the Patent Examiner by stating that no prior art showed an additive result in combining ibuprofen with an opioid, when prior art in Arnold's possession showed otherwise. Applicants further misled the Patent Examiner by not disclosing the Wyeth Patent as prior art and by not disclosing the fact that they had copied the majority of their patent application word for word from that prior art patent. These failures to disclose highly material information to the Patent Examiner and misleading statements to the Patent Examiner were done intentionally to mislead the Patent Examiner and keep the Examiner from seeing prior art which the Examiner would have concluded made Arnold's claims invalid, and in keeping the Patent Examiner from seeing that Arnold had done no work of his own but had instead copied his patent application.

ANSWER: Plaintiffs deny the allegations in paragraph 18.

19. Applicants knowingly and deliberately defrauded the PTO in the course of the patent prosecution that resulted in the issuance of the '252 Patent.

ANSWER: Plaintiffs deny the allegations in paragraph 19.

20. But for Applicants' fraud in the course of the patent prosecution, the PTO would not have issued the '252 Patent.

ANSWER: Plaintiffs deny the allegations in paragraph 20.

21. Applicants lack of disclosure of highly material prior art of which Applicants were aware, their lack of disclosure that Applicants had copied another patent, and Applicants' misrepresentations to the Patent Examiner constitute inequitable conduct which render the '252 Patent and all of its claims unenforceable.

ANSWER: Plaintiffs deny the allegations in paragraph 21.

Counterclaim Defendants' Improper Enforcement of the '252 Patent Through Wrongful Listing of the '252 Patent in the Orange Book and Improper Filing and Maintenance of Sham Litigation against Teva

22. Knoll asserts it is the owner of Approved New Drug Application ("NDA") No. 20-716, by which the FDA first granted approval for hydrocodone/ibuprofen, a combination analgesic that Knoll has marketed under the tradename Vicoprofen.®

ANSWER: Plaintiffs admit the allegations of paragraph 22.

23. Knoll listed the '252 Patent in the Orange Book as covering NDA No. 20-716 (Vicoprofen®). In 1997, Knoll commenced sales of its Vicoprofen® product in the United States.

ANSWER: Plaintiffs admit the allegations of paragraph 23.

24. On or about November 10, 2000, Teva filed with the FDA an ANDA which, as amended, sought approval to manufacture, market, and sell generic hydrocodone/ibuprofen products in the United States prior to the expiration of the '252 Patent. Because Knoll had listed the '252 Patent in the Orange Book, Teva included in its ANDA a Paragraph IV certification with

respect to the '252 Patent. The generic hydrocodone/ibuprofen products Teva sought approval to sell are bioequivalent to Vicoprofen®.

ANSWER: Plaintiffs admit that on or about November 10, 2002 Teva filed with the FDA an ANDA which, as amended, sought approval to manufacture, market, and sell generic hydrocodone/ibuprofen products. Plaintiffs state that the remaining allegations of paragraph 24 are a legal conclusion to which no answer is required.

25. On or about January 23, 2001, Teva, in accordance with 35 U.S.C. § 355(j)(2)(B), gave notice to Knoll and the Arnold LLP that it had filed ANDA No. 76-023 with the FDA seeking the FDA's approval to manufacture and sell its proposed hydrocodone/ibuprofen tablets. In its Notice, Teva certified pursuant to Paragraph IV of 21 U.S.C. § 355(j)(2)(A)(vii) that the '252 Patent was invalid, unenforceable and not infringed.

ANSWER: Plaintiffs admit that on or about January 23, 2001, Teva, in accordance with 35 U.S.C. § 355(j)(2)(B), gave notice to Knoll that it had filed ANDA No. 76-023 with the FDA seeking the FDA's approval to manufacture and sell its proposed hydrocodone/ibuprofen tablets. Plaintiffs deny that Teva gave notice the Arnold LLP that it had filed ANDA No. 76-023 with the FDA seeking the FDA's approval to manufacture and sell its proposed hydrocodone/ibuprofen tablets. Plaintiffs lack sufficient knowledge to form a belief as to the truth of the remaining allegations in paragraph 25 and therefore deny the same.

26. On or about March 8, 2001, Knoll and the Arnold LLP commenced a lawsuit (the "Sham Infringement Action") against Teva in the Northern District of Illinois, alleging that Teva infringed the '252 Patent because Teva sought FDA approval of Teva's ANDA to engage in the commercial manufacture, use, or sale of its generic hydrocodone/ibuprofen product prior to the expiration of the '252 Patent.

ANSWER: Plaintiffs admit that on or about March 8, 2001 Knoll and the Arnold LLP commenced a lawsuit against Teva in the Northern District of Illinois, alleging that Teva infringed the '252 Patent. Plaintiffs deny the remaining allegations in paragraph 26.

27. By filing and serving the Sham Infringement Action, Knoll and the Arnold LLP triggered the automatic 30-month stay period that prohibited the FDA from granting final approval of Teva's ANDA for 30 months following Knoll's receipt of Teva's Paragraph IV certification, unless Teva were to obtain a favorable judgment in the infringement action before the end of the 30-month period. Absent a court judgment in Teva's favor, the 30-month stay would have remained in place until July 23, 2003.

ANSWER: Plaintiffs deny the allegations in paragraph 27.

28. On or about September 12, 2002, the Court entered summary judgment in Teva's favor in the infringement action. That judgment terminated the 30-month stay.

ANSWER: Plaintiffs admit the allegations in paragraph 28.

29. On or about April 14, 2003, the FDA granted final approval to Teva's ANDA for its generic hydrocodone/ibuprofen product and Teva commenced sales of its generic hydrocodone/ibuprofen product in the United States.

ANSWER: Plaintiffs lack sufficient knowledge to form a belief as to the truth of the allegations in paragraph 29 and therefore deny the same.

30. On May 19, 2004, the United States Court of Appeals for the Federal Circuit reversed the trial court's grant of summary judgment in the Sham Infringement Action and remanded the case for further proceedings because disputed facts regarding secondary considerations rendered the case inappropriate for summary judgment. The Federal Circuit did not decide whether the '252 Patent is obvious or otherwise invalid or unenforceable. Knoll and the Arnold LLP continue to prosecute the Sham Infringement Action today.

ANSWER: Plaintiffs admit that on May 19, 2004 the United States Court of Appeals for the Federal Circuit reversed the trial court's grant of summary judgment. Plaintiffs deny the remaining allegations in paragraph 30.

31. Prior to the listing of the '252 Patent in the Orange Book and prior to Counterclaim Defendants' commencement of and maintenance of the Sham Infringement Action,

Knoll and the Arnold LLP knew that the '252 Patent had been issued as a result of fraud upon the PTO and that, but for the fraud, the PTO would not have issued the '252 Patent.

ANSWER: Plaintiffs deny the allegations of paragraph 31.

32. Prior to the listing of the '252 Patent in the Orange Book and prior to Counterclaim Defendants' commencement of and maintenance of the Sham Infringement Action, Knoll and the Arnold LLP knew that the '252 Patent was unenforceable on the grounds that Applicants engaged in inequitable conduct in connection with the prosecution of the '252 Patent.

ANSWER: Plaintiffs deny the allegations in paragraph 32.

33. Counterclaim Defendants' filing and maintenance of the '252 Patent in the Orange Book are wrongful, objectively baseless, subjectively intended to interfere directly with the business relationships of Teva and to otherwise injure Teva and consumers, and a sham, as the '252 Patent is unenforceable and invalid. The wrongful listing of the '252 Patent in the Orange Book required Teva to provide a Paragraph IV certification and permitted Counterclaim Defendants to maintain the Sham Infringement Action.

ANSWER: Plaintiffs deny the allegations in paragraph 33.

34. Counterclaim Defendants' filing and maintenance of the Sham Infringement Action against Teva are objectively baseless in that no reasonable person could realistically expect success on the merits of the Sham Infringement Action knowing, as Counterclaim Defendants do, that the '252 Patent is not enforceable due to the inequitable conduct of Arnold before the PTO, and knowing, as Counterclaim Defendants do, that the '252 Patent is invalid due to prior art. Counterclaim Defendants had no probable cause to commence, and they have no probable cause to prosecute or maintain, the Sham Infringement Action.

ANSWER: Plaintiffs deny the allegations in paragraph 34.

35. Counterclaim Defendants commenced, and are prosecuting and maintaining, the Sham Infringement Action with the subjective and wrongful intent to interfere directly with the business relationships of Teva through the improper use of the judicial process and to maintain a monopoly. Counterclaim Defendants are prosecuting the Sham Infringement Action maliciously, not to obtain a favorable outcome on the merits of the claims asserted, but to achieve an anticompetitive objective through the use - and abuse - of governmental processes.

ANSWER: Plaintiffs deny the allegations of paragraph 35.

36. Counterclaim Defendants commenced, and are prosecuting and maintaining, the Sham Infringement Action even though they know (and knew at the time of filing) that the '252 Patent was obtained by fraud on the PTO and would not have issued but for that fraud.

ANSWER: Plaintiffs deny the allegations of paragraph 36.

Pattern Of Sham Conduct And Continuing Violation

37. The pattern of anticompetitive conduct and practice complained of herein includes without limitation:

a) Arnold's knowingly engaging in fraudulent and/or inequitable conduct in the prosecution of the '252 Patent;

b) Counterclaim Defendants' wrongfully and baselessly causing the '252 Patent to be listed in the Orange Book with knowledge of the fraudulent and/or inequitable conduct in the prosecution of the '252 Patent; and

c) Counterclaim Defendants' prosecuting the objectively baseless Sham Infringement Action with the subjective intent to prevent, impede, or delay Teva's entry into the Relevant Market and directly to interfere with its business relationships, through the use (and abuse) of the governmental process as opposed to the outcome of that process.

ANSWER: Plaintiffs deny the allegations of paragraph 37.

38.. Counterclaim Defendants filed and maintained the sham Orange Book listing and prosecuted the Sham Infringement Action with the purpose and specific intent of willfully and unlawfully attempting to monopolize sales of hydrocodone/ibuprofen products in the United States.

ANSWER: Plaintiffs deny the allegations of paragraph 38.

39. Applicants' fraudulent and/or inequitable conduct in connection with the prosecution of the '252 Patent, Counterclaim Defendants' wrongful listing of the '252 Patent in the Orange Book, and Counterclaim Defendants' continuous prosecution of the Sham Infringement Action constitute a pattern of baseless, sham conduct and litigation positions that is designed to injure, has injured, and continues to injure Teva.

ANSWER: Plaintiffs deny the allegations of paragraph 39.

40. The ongoing and continuous course of anticompetitive conduct and practice complained of herein constitutes affirmative and willful acts of attempted monopolization by Counterclaim Defendants.

ANSWER: Plaintiffs deny the allegations of paragraph 40.

41. The conduct complained of herein constituted an ongoing and continuous course of anticompetitive conduct that was comprised of separate, overt acts that continuously inflicted ongoing, uninterrupted, and continuous antitrust injury on Teva.

ANSWER: Plaintiffs deny the allegations of paragraph 41.

There Was a Dangerous Probability that Counterclaim Defendants Would Succeed in their Attempt to Monopolize

42. The relevant product market in which to assess the anticompetitive effect of Counterclaim Defendants' conduct is the market for hydrocodone/ibuprofen products, which consists of Vicoprofen® and generic bioequivalent versions of Vicoprofen .

ANSWER: Plaintiffs deny the allegations of paragraph 42.

43. There is a unique competitive relationship between a brand-name pharmaceutical product and generic bioequivalent versions of that product.

ANSWER: Plaintiffs deny the allegations of paragraph 43.

44. At all times since Teva launched sales of its hydrocodone/ibuprofen product in the United States, Teva has sold its product at a significant discount to the price of Vicoprofen®. The entry of lower-cost generic bioequivalent versions of Vicoprofen®, was and is a direct consumer benefit. Correspondingly, actions by Counterclaim Defendants improperly to delay generic entry and protect their monopoly were designed to benefit themselves at the expense of consumers forced to pay higher prices for hydrocodone/ibuprofen products.

ANSWER: Plaintiffs deny the allegations of paragraph 44.

45. Because of this competitive relationship between Vicoprofen® and its generic bioequivalent drug rivals, such products comprise a distinct relevant product market for antitrust purposes. Other combination analgesics are available in the United States, but the presence of those products is not sufficient to prevent the anticompetitive effect that Counterclaim Defendants' exclusionary conduct attempted to produce and came dangerously close to producing.

ANSWER: Plaintiffs deny the allegations of paragraph 45.

46. The relevant geographic market is the United States. The FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals occurs on a nationwide basis, establish the boundaries of the geographic market.

ANSWER: Plaintiffs deny the allegations in paragraph 46.

47. Counterclaim Defendants took a number of affirmative acts in furtherance of their attempt to monopolize, as alleged herein. Those actions were intended to give Counterclaim Defendants the power to control the price of hydrocodone/ibuprofen products in the United States and exclude competition by delaying the entry of lower-cost generic hydrocodone/ibuprofen products. As a result of those actions, there was a dangerous probability that Counterclaim Defendants would succeed in improperly maintaining their monopoly.

ANSWER: Plaintiffs deny the allegations of paragraph 47.

48. Counterclaim Defendants' wrongful actions forced Teva to file a Paragraph IV certification to the '252 Patent in connection with its ANDA, even though the '252 Patent should never have issued and should never have been listed in the Orange Book, and thus no Paragraph IV certification should have been required. As a direct and proximate result of Counterclaim Defendants' forcing Teva to file a Paragraph IV certification, Counterclaim Defendants were able to misuse the Hatch Waxman Amendments to obtain an automatic 30month stay of FDA approval of Teva's ANDA. If Counterclaim Defendants had not wrongfully listed the `252 Patent in the Orange Book, Teva would not have been required to file a Paragraph IV certification, and Counterclaim Defendants could not have obtained a 30-month stay. By improperly obtaining the 30-month stay, Counterclaim Defendants misused the Hatch Waxman Amendments to exclude any other company from selling hydrocodone/ibuprofen products in the United States.

ANSWER: Plaintiffs deny the allegations of paragraph 48.

49. Counterclaim Defendants' wrongful actions improperly maintained their monopoly power in the sale of hydrocodone/ibuprofen products in the United States by wrongfully excluding generic entry while the stay remained in effect. Counterclaim Defendants were the only sellers of hydrocodone-ibuprofen products in the United States at the time of their actions, and their actions meant that no one else could sell such products in the United States during the pendency of the 30-month stay, even if ANDA applicants had been able to satisfy all the regulatory requirements for sale of prescription pharmaceutical products in the United States. For so long as Counterclaim Defendants could delay generic entry, they could continue to charge supracompetitive prices for Vicoprofen®.

ANSWER: Plaintiffs deny the allegations of paragraph 49.

50. Counterclaim Defendants' actions were sufficient to actually monopolize sales of hydrocodone/ibuprofen products in the United States. Counterclaim Defendants improperly obtained the 30-month stay, which guaranteed that no other hydrocodone/ibuprofen product would compete with their Vicoprofen® product during the pendency of the stay. Several months before the 30-month stay would have expired of its own terms, the FDA concluded that Teva's hydrocodone/ibuprofen product satisfied all the regulatory requirements for sale in the United States. Had the stay remained in effect for the full 30 months, the FDA could not have granted Teva final approval to commence selling its product when it finished its review. Rather, FDA could only have given Teva tentative approval, which would not have allowed Teva to sell its product, until the stay ended. Thus, Counterclaim Defendants' conduct would actually have excluded Teva's product from the market and would have improperly maintained their monopoly.

ANSWER: Plaintiffs deny the allegations of paragraph 50.

51. The only reason Counterclaim Defendants did not succeed in improperly extending their monopoly in sales of hydrocodone/ibuprofen products is that Teva obtained summary, judgment in its favor in the Sham Litigation Action before the end of the 30-month period, and before the FDA completed its review of Teva's ANDA. That favorable court decision terminated the 30-month stay early. As a result, Teva was able to start marketing its product once the FDA concluded its review and approved Teva's ANDA. But for Teva's success in terminating the 30-month stay early, Counterclaim Defendants' actions would have resulted in actual monopolization. Counterclaim Defendants' nearly-successful attempt to monopolize came dangerously close to succeeding and independently violates Section 2 of the Sherman Act.

ANSWER: Plaintiffs deny the allegations of paragraph 51.

Teva Has Suffered Antitrust Injury as a Result of Counterclaim Defendants' Illegal and Anticompetitive Conduct

52. By engaging Teva in their objectively baseless litigation, Knoll and the Arnold LLP have unlawfully and willfully attempted to maintain a monopoly in the sale of hydrocodone/ibuprofen products in the United States.

ANSWER: Plaintiffs deny the allegations of paragraph 52.

53. By improperly using this baseless litigation to obtain extended market exclusivity from the FDA, Knoll and the Arnold LLP attempted to maintain their ability to control the pricing of hydrocodone/ibuprofen products in the United States and to exclude competition in sales of those products. By attempting to keep Teva from participating in the sale of hydrocodone/ibuprofen products in the United States, Knoll and the Arnold LLP attempted to deprive consumers of a lower cost alternative to Vicoprofen® and attempted to directly injure competition in the market.

ANSWER: Plaintiffs deny the allegations of paragraph 53.

54. Knoll and the Arnold LLP have injured Teva by forcing Teva to incur substantial costs in defending against a meritless and baseless lawsuit that wrongfully and in bad faith seeks to enforce the invalid and unenforceable '252 Patent for anticompetitive purposes. Teva's injuries flow directly from the injury to competition, and both Teva's injuries and the injury to competition have resulted directly from Knoll's and the Arnold LLP's anticompetitive conduct. Knoll's and the Arnold LLP's improper and anticompetitive conduct was a direct and proximate cause of the threatened injuries to competition and the injury to Teva complained of in these counterclaims.

ANSWER: Plaintiffs deny the allegations of paragraph 54.

55. The injury Knoll and the Arnold LLP have inflicted on Teva through their improper and anticompetitive conduct constitute antitrust injury for which Teva is entitled to recover three times its actual damages pursuant to the federal antitrust laws.

ANSWER: Plaintiffs deny the allegations of paragraph 55.

First Counterclaim

Declaratory Judgment of Invalidity of the '252 Patent

56. Teva repeats and re-alleges paragraphs 1-55 above as though fully set forth herein.

ANSWER: Plaintiffs repeat and re-allege the answers to paragraphs 1-55 above as though fully set forth herein.

57. An actual controversy exists between Teva and Knoll and the Arnold LLP concerning the validity of the '252 Patent, which requires a declaration of rights by this Court.

ANSWER: Plaintiffs admit the allegations of paragraph 57.

58. All claims of the '252 Patent are invalid for failing to comply with the requirements of the Patent Laws of the United States, 35 U.S.C. §§ 101, et seq.

ANSWER: Plaintiffs deny the allegations of paragraph 58.

Second Counterclaim

Declaratory Judgment of Unenforceability of the '252 Patent

59. Teva repeats and re-alleges paragraphs 1-58 above as though fully set forth herein.

ANSWER: Plaintiffs repeat and re-allege the answers to paragraphs 1-58 above as though fully set forth herein.

60. An actual controversy exists between Teva and Knoll and the Arnold LLP concerning the enforceability of the '252 Patent, which requires a declaration of rights by this Court.

ANSWER: Plaintiffs admit the allegations of paragraph 60.

61. The '252 Patent and all the claims thereof are unenforceable due to inequitable conduct by Arnold or his agents in connection with procurement of the '252 Patent.

ANSWER: Plaintiffs deny the allegations of paragraph 61.

62. Arnold and his agents breached their duty of candor in dealing with the PTO by knowingly withholding material prior art during prosecution of the '252 Patent, with the intent to mislead the; PTO.

ANSWER: Plaintiffs deny the allegations of paragraph 62.

63. The material prior art of which Arnold was aware, and which he knew was highly material, but which Arnold failed to disclose to the PTO, includes: U.S. Patent No. 4,466,963 ("the Wyeth patent"), the published European Patent Application No. 0068838 (the "Upjohn Application"), Knoll's Vicodin® product (hydrocodone 5 mg./acetaminophen 500 mg.), U.S. Patent No. 4,486,436 ("the '436 patent"), U.S. Patent No. 4,479,956 ("the '956 patent), published articles by Dr. William Beaver and a published article by Dr. Theresa Ferrer-Brechner. Applicants also made material and intentional misrepresentations and misleading statements to the PTO regarding the work of Dr. Stephen Cooper regarding combinations of ibuprofen and codeine, and in asserting that no prior art showed an increased pain-relieving effect in combining ibuprofen with an opioid.

ANSWER: Plaintiffs deny the allegations of paragraph 63.

64. The '252 Patent is therefore rendered unenforceable by inequitable conduct.

ANSWER: Plaintiffs deny the allegations of paragraph 64.

Third Counterclaim

Attempted Monopolization – Sham Litigation

65. Teva repeats and re-alleges paragraph 1-64 above as though fully set forth herein.

ANSWER: Plaintiffs repeat and re-allege the answers to paragraphs 1-64 above as though fully set forth herein.

66. Knoll and the Arnold LLP have illegally attempted to monopolize the sale of hydrocodone/ibuprofen products in the United States. They have engaged in exclusionary and predatory conduct – including without limitation the filing and maintenance of sham litigation – with a specific intent to monopolize, and with a dangerous probability of success.

ANSWER: Plaintiffs deny the allegations of paragraph 66.

67. The lawsuit Knoll and the Arnold LLP filed and have maintained against Teva constitutes sham litigation, in that it is objectively baseless and is motivated by subjective bad intent.

ANSWER: Plaintiffs deny the allegations of paragraph 67.

68. This unlawful attempted monopolization threatened to work, and has worked, a substantial adverse impact on competition.

ANSWER: Plaintiffs deny the allegations of paragraph 68.

69. By filing this baseless lawsuit, Knoll and the Arnold LLP have wrongfully invoked federal statutory provisions and FDA regulations as part of their attempt to prevent Teva from commencing sales of hydrocodone/ibuprofen products in the United States in competition with Knoll.

ANSWER: Plaintiffs deny the allegations of paragraph 69.

70. The Arnold LLP's and Knoll's unlawful attempted monopolization has caused, and will continue to cause, actual and substantial injury to Teva.

ANSWER: Plaintiffs deny the allegations of paragraph 70.

71. The injury to Teva resulting from Knoll's and the Arnold LLP's anticompetitive conduct constitutes antitrust injury.

ANSWER: Plaintiffs deny the allegations of paragraph 71.

72. Teva is entitled to recover three times its actual damages resulting from Knoll's and the Arnold LLP's anticompetitive conduct, costs, and attorneys fees pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15.

ANSWER: Plaintiffs deny the allegations of paragraph 72.

Fourth Counterclaim

Attempted Monopolization – Walker Process

73. Teva repeats and re-alleges paragraphs 1-72 above as though fully set forth herein.

ANSWER: Plaintiffs repeat and re-allege the answers to paragraphs 1-72 above as though fully set forth herein.

74. Knoll and the Arnold LLP have illegally attempted to monopolize the sale of hydrocodone/ibuprofen products in the United States. They have engaged in such exclusionary and predatory conduct - including without limitation the filing and maintenance of a lawsuit to enforce a patent that they know was obtained by fraud - with a specific intent to monopolize, and with a dangerous probability of success.

ANSWER: Plaintiffs deny the allegations of paragraph 74.

75. The '252 Patent was fraudulently procured through misrepresentations, misleading, statements, and omissions of material prior art to the PTO by Applicants. Applicants made these misrepresentation and omissions to the PTO during the prosecution of the '252 Patent with the intent of deceiving the PTO, in order to obtain a patent.

ANSWER: Plaintiffs deny the allegations of paragraph 75.

76. Applicants failed to disclose at least the following material prior art, of which they were aware and which they knew was highly material, to the PTO: (a) the Wyeth patent, (b) the Upjohn Application, (c) Knoll's Vicodin® product, (d) the '436 patent, (e) the '956 patent, (f) the 1984 Beaver articles and (g) the Ferrer-Brechner article. Applicants also made material and intentional misrepresentations and misleading statements to the PTO regarding the work of Dr. Stephen Cooper regarding combinations of ibuprofen and codeine, and in asserting that no prior art showed an increased pain-relieving effect in combining ibuprofen and an opioid. On

information and belief, Applicants' material misrepresentations to the PTO were knowing and intentional.

ANSWER: Plaintiffs deny the allegations of paragraph 76.

77. The PTO relied upon Applicants' misrepresentations and omissions in its decision to issue the '252 Patent. Had these material prior art references been disclosed or had the misrepresentations made by Applicants to the PTO not been made, the '252 Patent would not have issued.

ANSWER: Plaintiffs deny the allegations of paragraph 77.

78. Counterclaim Defendants knew that the '252 Patent had been fraudulently procured when they took steps to enforce the '252 Patent by listing it in the Orange Book and by filing and maintaining this lawsuit.

ANSWER: Plaintiffs deny the allegations of paragraph 78.

79. By filing this baseless lawsuit, Knoll and the Arnold LLP have wrongfully invoked federal statute and FDA regulations as part of their attempt to prevent Teva from commencing sales of hydrocodone/ibuprofen products in the United States in competition with Knoll.

ANSWER: Plaintiffs deny the allegations of paragraph 79.

80. Knoll and the Arnold LLP have forced Teva to incur substantial costs in defending against this objectively baseless lawsuit.

ANSWER: Plaintiffs deny the allegations of paragraph 80.

81. This unlawful attempted monopolization threatened to work and has worked a substantial adverse impact on competition.

ANSWER: Plaintiffs deny the allegations of paragraph 81.

82. Knoll's and the Arnold LLP's unlawful attempted monopolization has caused, and will continue to cause, actual and substantial injury to Teva.

ANSWER: Plaintiffs deny the allegations of paragraph 82.

83. The injury to Teva resulting from Knoll's and the Arnold LLP's anticompetitive conduct constitutes antitrust injury.

ANSWER: Plaintiffs deny the allegations of paragraph 83.

84. Teva is entitled to recover three times its actual damages resulting from Knoll's and the Arnold LLP's anticompetitive conduct, costs, and attorneys fees pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15.

ANSWER: Plaintiffs deny the allegations of paragraph 84.

PLAINTIFFS' ADDITIONAL AND AFFIRMATIVE DEFENSES

1. Each of Teva's Counterclaims, in whole or in part, fails to state a claim upon which relief can be granted.

2. Teva does not have standing to assert its counterclaims against Plaintiffs.

3. Teva has not sustained any cognizable injury or antitrust injury.

4. Teva did not have the right to lawfully sell its hydrocodone/ibuprofen product prior to May 2003.

5. Teva's counterclaims are barred in whole or in part by laches and/or estoppel.

6. Teva's counterclaims are barred in whole or in part by the applicable statute of limitations.

7. The '252 patent is valid and enforceable.

8. Plaintiffs acted in good faith during the prosecution of the '252 Patent.

9. Plaintiffs did not make any material misrepresentations or omissions to the United States Patent and Trademark Office during the prosecution of the '252 Patent.

10. Plaintiffs actions in brining this lawsuit are fully justified and done in good faith.

11. Plaintiffs have the right to petition the Government for redress of grievances under the First Amendment of the U.S. Constitution.

WHEREFORE: Plaintiffs pray for judgment:

a) Dismissing Teva's counterclaims with prejudice;

b) Awarding to Plaintiffs their costs, attorneys' fees and expenses incurred in defending against these counterclaims;

c) Rewarding to Plaintiffs the relief sought in the Complaint; and

d) Granting Plaintiffs such other relief as the Court deems appropriate.

Date: October 20, 2004

Knoll Pharmaceuticals Company, Inc.

One of their attorneys

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CERTIFICATE OF SERVICE

I hereby certify that on October, 20, 2004, a copy of, Plaintiffs REPLY TO COUNTERCLAIMS was served upon the following as indicated below:

VIA MESSENGER

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